PATENT COOPERATION TREATY

PCT

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
1038-1059MIS		
International application No.	International filing date *(day/month/year)*	Priority date *(day/month/year)*
PCT/CA00/00811	11/07/2000	15/07/1999
International Patent Classification (IPC) or national classification and IPC A61K39/00		
Applicant AVENTIS PASTEUR LIMITED		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

   ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the report
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☐ Lack of unity of invention
   - V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations suporting such statement
   - VI ☒ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☒ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
14/02/2001	18.09.2001
Name and mailing address of the international preliminary examining authority: European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer BROCHADO GARGANTA, M Telephone No. +49 89 2399 8935

Form PCT/IPEA/409 (cover sheet) (January 1994)

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/CA00/00811

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:
Description, pages:

1-35 as originally filed

Claims, No.:

1-29 as originally filed

Drawings, sheets:

1/18-18/18 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:

☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application.

   ☒ claims Nos. 29.

because:

   ☒ the said international application, or the said claims Nos. 29, with respect to industrial applicability relate to the following subject matter which does not require an international preliminary examination (*specify*): **see separate sheet**

   ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☐ no international search report has been established for the said claims Nos. .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the standard.

   ☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

   Novelty (N) Yes: Claims 1-29

	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-29
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-28
	No:	Claims	

2. Citations and explanations
see separate sheet

VI. Certain documents cited

1. Certain published documents (Rule 70.10)

and / or

2. Non-written disclosures (Rule 70.9)

see separate sheet

VIII. Certain observations on the international application

The following observations on the clarity of the claims, description, and drawings or on the question whether the claims are fully supported by the description, are made:
see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. Claim 29, relates to a method for immunising a host against a disease. It relates to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(i) PCT).

Re Item V

Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Reference is made to the following documents:

   (A) WO 96 34960 A

   (B) WO 94 21290 A

   (C) Barenkamp S J.: Infection and Immunity, AMERICAN SOCIETY FOR MICROBIOLOGY. WASHINGTON,US, vol. 64, no. 4, April 1996 (1996-04), pages 1246-1251

2. Novelty

2.1 The subject-matter of claims 1 and 8, relating to a multi-valent immunogenic composition for conferring protection in a host against a disease caused by both *Haemophilus influenzae* and *Moraxella catarrhalis*, is new in the sense of Article 33(2) PCT, because an immunogenic composition with such features is not known from the prior art. The same applies to dependent claims 2-7 and 9-28.

The method of immunising a host against a disease caused by infection with both *Haemophilus influenza* and *Moxarella catrrhalis*, by adminestering to the host the

claimed composition, is new in the sense of Article 33(2) PCT.

3. Inventive step

3.1 Document A discloses an immunogenic composition comprising an isolated and purified outer membrane protein of a *Moxarella* strain with a molecular mass of 200 KDa (see claim 28). No reference is done to *Haemophilus influenza*. Moreover, the function of this membrane protein is still not well characterised and no reference is made to an adhesin.

Document B discloses a vaccine against a disease caused by non-typeable *Haemophilus influenza* comprising an effective amount of a high molecular weight protein of *Haemophilus influenza* (see claim 1). No reference is made to a *Moxarella* strain.

Document C refers to the identification of a second family of high-molecular-weight adhesion proteins expressed by non-typable *Haemophilus influenza*, wherein it is suggested that there may be the possibility of developing vaccines based upon a combination of high molecular immunogenic proteins, which would be protective against diseases caused by non-typable *Haemophilus influenza*. No reference is done to *a Moxarella* strain.

The difference between the subject-matter of claims 1 and 8 and the disclosures in documents A or B or C, is the fact that the composition comprises antigens from both *H. Influenza* and *M. catarrhalis*.

Thus, the problem to be solved by the present application is to provide an improved composition for conferring protection against both *H. Influenza* and *M. catarrhalis*.

No reference was given for combining both antigens. Thus, it would not be obvious for the skilled person to combine the disclosures in documents A and B or A and C and arrive in this way to the features of these claims.

Moreover, otitis media is the most common illness of early childhood. infections account for about 30% of the cases of acute otitis media and about 60% of chronic

otitis media. infections account for an additional 15-20% of acute otitis media. Thus, a combination of antigens against both bacteria would be more efficient for protection against otitis media.

Thus, claims 1 and 8 are considered to be based on an inventive step as required by Article 33(3) PCT. The same applies to dependent claims 2-7 and 9-28 and to independent claim 29, relating to a method of immunising a host by administering the claimed composition.

4. For the assessment of the present claim 29 on the question whether it is industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

Re Item VI
Certain documents cited

1. The intermediate document cited in the International Search Report (WO 00 35477 A) is not considered to be relevant for the examination on novelty and inventive step of the present application. However, it could be used if the priority of the present application is not validly claimed.

Re Item VIII
Certain observations on the international application

1. The use of the wording "about" in connection with a range of values (see claim 25) is ambiguous and renders the scope of protection unclear (Article 6 PCT).